



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION 5  
77 WEST JACKSON BOULEVARD  
CHICAGO, IL 60604-3590

MAY 14 2008

REPLY TO THE ATTENTION OF:

AE-17J

**CERTIFIED MAIL**  
**RETURN RECEIPT REQUESTED**

Ryan McGill, Site Leader  
Dow Agrosciences, L.L.C.  
305 N. Huron Avenue  
Harbor Beach, Michigan 48441

Re: Finding of Violation  
Dow Agrosciences  
Harbor Beach, MI

Dear Mr. McGill:

The U.S. Environmental Protection Agency is issuing the enclosed Finding of Violation (FOV) to Dow Agrosciences, L.L.C. (you). We find that you have violated Section 112 of the Clean Air Act, 42 U.S.C. § 7412, at your Harbor Beach, Michigan facility.

We have several enforcement options under Section 113(a)(3) of the Clean Air Act, 42 U.S.C. § 7413(a)(3). These options include issuing an administrative compliance order, issuing an administrative penalty order, and bringing a judicial civil or criminal action.

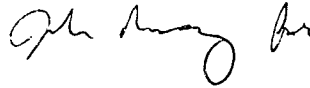
We are offering you an opportunity to confer with us about the violations alleged in the FOV. The conference will give you the opportunity to present information on the specific findings of violation, the efforts you have taken to comply, and the steps you will take to prevent future violations.

Please plan for your facility's technical and management personnel to attend the conference to discuss compliance measures and commitments. You may have an attorney represent you at this conference.

The EPA contacts in this matter are Constantinos Loukeris and Kathy Memmos. You may call them at (312) 353-6198 and (312) 353-4293 to request a conference.

You should make the request within 10 calendar days following receipt of this letter. We should hold any conference within 30 calendar days following receipt of this letter.

Sincerely,

A handwritten signature in black ink, appearing to read "Cheryl L. Newton".

Cheryl L. Newton, Acting Director  
Air and Radiation Division

Enclosure

cc: Mark Reed, MDEQ

United States Environmental Protection Agency Region 5

IN THE MATTER OF:	)	
	)	
Dow Agrosciences, L.L.C.	)	FINDING OF VIOLATION
Harbor Beach, Michigan	)	
	)	EPA-5-08-MI-14
	)	
Proceedings Pursuant to	)	
the Clean Air Act,	)	
42 U.S.C. §§ 7401 et seq.	)	

FINDING OF VIOLATION

The U.S. Environmental Protection Agency finds that Dow Agrosciences, L.L.C. (Dow or you) is violating Section 112 of the Clean Air Act (the Act), 42 U.S.C. § 7412. Specifically, Dow is violating the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG as follows:

**Regulatory Authority**

1. The NESHAP for Pharmaceuticals Production was proposed on April 2, 1997 and became final on September 21, 1998. The owner or operator of an existing affected source must comply with the provisions of the NESHAP no later than October 21, 2002, as required under 40 C.F.R. § 63.1250(f)(1). The owner or operator of a new or reconstructed affected source must comply with the provisions of the NESHAP on August 29, 2000 or upon startup, whichever is later, as required under 40 C.F.R. § 63.1250(f)(2).
2. The NESHAP for Pharmaceuticals Production, at 40 C.F.R. § 63.1250(a), defines an affected source as manufacturing operations that: a) manufacture a pharmaceutical product; b) are located at a plant site that is a major source as defined in Section 112(a) of the Act; and c) process, use or produce Hazardous Air Pollutants (HAPs).
3. The NESHAP for Pharmaceuticals Production sets out Applicability provisions at 40 C.F.R. § 63.1250, Definitions at 40 C.F.R. § 63.1251, and General Standards at 40 C.F.R. § 63.1252.
4. The NESHAP for Pharmaceuticals Production provides Standards for Storage Tanks at 40 C.F.R. § 63.1253, Process Vents at 40 C.F.R. § 63.1254, Equipment Leaks at 40 C.F.R. § 63.1255, and Wastewater at 40 C.F.R. § 63.1256.

5. The NESHAP for Pharmaceuticals Production specifies Test Methods and Compliance Procedures at 40 C.F.R. § 63.1257, Monitoring Requirements at 40 C.F.R. § 63.1258, and Recordkeeping Requirements at 40 C.F.R. § 63.1259.
6. The NESHAP for Pharmaceuticals Production sets out reporting requirements at 40 C.F.R. § 63.1260, including, at 40 C.F.R. § 63.1260(f), that the owner or operator of an affected source submit a Notification of Compliance Status Report, within 150 days of the compliance date, demonstrating timely compliance with the applicable requirements set out above, and, at 40 C.F.R. § 63.1260(g), that the owner or operator of an affected source submit a Periodic report, within 240 days of due date of the Notification of Compliance Status Report, or as otherwise required.
7. The NESHAP, at 40 C.F.R. § 63.4(a)(1), provides that no owner or operator subject to the provisions of this part shall operate any affected source in violation of the requirements of this part except under an extension of compliance granted by the Administrator, State with an approved permit program, or by the President under Section 112(i)(4) of the Act.
8. The NESHAP, at 40 C.F.R. § 63.6(e)(3)(i), requires the owner or operator of an affected source to develop and implement a written startup, shutdown, and malfunction plan that describes, in detail, procedures for operating and maintaining the source during periods of startup, shutdown, and malfunction and a program of corrective action for malfunctioning process, air pollution control and monitoring equipment used to comply with the relevant standard.

### **Facility Information**

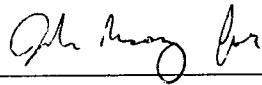
9. Dow owns and operates a chemical plant at their Harbor Beach, Michigan facility.
10. At the Harbor Beach facility, Dow has a manufacturing operation that produces Spinosad, a pharmaceutical product, and a Spinosyn J/L intermediate, a pharmaceutical active ingredient, within the meaning of the NESHAP for Pharmaceuticals Production. The Dow facility in Harbor Beach, Michigan is a major source as defined in Section 112(a) of the Act. Dow uses HAPs at various stages of its pharmaceutical manufacturing process. Therefore, Dow's Spinosad and Spinosyn J/L intermediate operations are subject to the requirements of the NESHAP for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG.
11. On February 29, 2008, Dow submitted the Pre-Compliance and Notification of Compliance Status reports stating that the pharmaceutical operations began in December 2003.

## Violations

12. Dow failed to determine whether the Spinosad and Spinosyn J/L intermediate operations at the Harbor Beach facility were subject to the requirements of the NESHAP for Pharmaceuticals Production at 40 C.F.R. Part 63, Subpart GGG by December 2003. This is a violation of 40 C.F.R. §§ 63.1250 and 63.1260.
13. Dow failed to submit a Notification of Compliance Status Report for the Spinosad and Spinosyn J/L intermediate manufacturing operations at the Harbor Beach facility within 150 days of December 2003. This is a violation of 40 C.F.R. § 63.1260(f).
14. Dow failed to submit a Periodic Report for the Spinosad and Spinosyn J/L intermediate manufacturing operations at the Harbor Beach plant within 240 days of due date of the Notification of Compliance Status Report. This is a violation of 40 C.F.R. § 63.1260(g).
15. Dow failed to identify any storage tanks associated with the Spinosad and Spinosyn J/L intermediate process. This is a violation of 40 C.F.R. § 63.1253.
16. Dow failed to choose a process vent standard to comply with for the Spinosad and Spinosyn J/L intermediate HAP emissions. This is a violation of 40 C.F.R. § 63.1254.
17. Dow failed to identify all components requiring Leak Detection and Repair monitoring per U.S. EPA Reference Method 21 or visual inspections. This is a violation of 40 C.F.R. § 63.1255.
18. Dow failed to identify all Points of Determination and wastewater that required control. This is a violation of 40 C.F.R. § 63.1256.
19. Dow failed to develop and implement a Startup, Shutdown, and Malfunction Plan and a Maintenance Wastewater Plan. This is a violation of 40 C.F.R. § 63.6(e)(3)(i) and 63.1256.
20. Dow failed to conduct performance testing on the 850-Thermal Treatment Unit (TTU), 855-TTU, 860-TTU, and 865-TTU. This is a violation of 40 C.F.R. § 63.1257.
21. Dow failed to conduct initial compliance demonstrations on five (5) process condensers and on any condensers acting as air pollution control devices. This is a violation of 40 C.F.R. § 63.1257.
22. Dow failed to monitor the required parameters for the control devices used in the Spinosad and Spinosyn J/L intermediate processes. This is a violation of 40 C.F.R. § 63.1258.

23. Dow failed to maintain records required by the various sections of the subpart depending on the compliance options chosen. This is a violation of 40 C.F.R. § 63.1259.
24. Dow operated an affected source in violation of the NESHAP for Pharmaceuticals Production, 40 C.F.R. Part 63, Subpart GGG. This is a violation of 40 C.F.R. § 63.4(a)(1).

Date: 5/14/08

  
Cheryl L. Newton, Acting Director  
Air and Radiation Division

CERTIFICATE OF MAILING

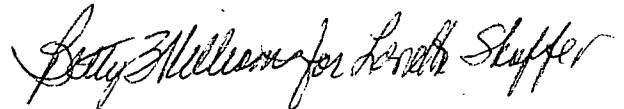
I, Loretta Shaffer, certify that I sent a Finding of Violation, No. EPA-5-08-MI-14, by Certified Mail, Return Receipt Requested, to:

Ryan McGill, Site Leader  
Dow Agrosiences, L.L.C.  
305 N. Huron Avenue  
Harbor Beach, Michigan 48441

I also certify that I sent copies of the Finding of Violation by first class mail to:

Mark Reed, District Supervisor  
Michigan Department of Environmental Quality – Air Quality Division  
Saginaw Bay District Office  
503 N. Euclid Avenue  
Bay City, Michigan 48706-2965

on the 15<sup>th</sup> day of May, 2008.



Loretta Shaffer, Secretary  
AECAS, (MI/WI)  
(312) 353-5723

CERTIFIED MAIL RECEIPT NUMBER: 70010320 00061447 2227